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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,537	04/23/2002	Balasulojini Karunanandaa	16516.130	4151

7590

07/14/2005

David R Marsh
Arnold & Porter
555 12th Street NW
Washington, DC 20004

EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/030,537	Applicant(s) KARUNANANDAA ET AL.	
	Examiner Russell Kallis	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-21, 25-27 and 30-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-21, 25-27 and 30-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>attached sequence report</u> . |

DETAILED ACTION

Claims 1-15, 22-24, 28-29 and 42-46 are canceled. Claims 16-21, 25-27 and 30-41 are pending and examined.

Claim Rejections - 35 USC § 112

Claims 21, 25-27 and 30-41 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/07/2004. Applicant's arguments filed 4/07/2005 have been considered but are not deemed persuasive.

Applicant asserts that they need not describe all things encompassed by the claims and that the written description requirement can be met by disclosure of sufficiently detailed and relevant identifying characteristics (response page 9 and 10). Applicant further contends that the disclosure of SEQ ID NO: 4 is a relevant identifying feature, and that the identification of SEQ ID NO: 1, 2, 3 and 4 are features that provide a basis for each and every nucleic acid molecule of the claimed genus (response page 10, lines 16-18).

There is no correlation between the structure of HES1 from yeast and any discrete function that is required for an adequate written description of a genus (See Example 14 of the Written Description Guidelines). Moreover there is no correlation between the structure or length of the amino acid sequence of SEQ ID NO: 35 (i.e. the HES1 from yeast) and SEQ ID NO: 33 encoded by the nucleic acid sequence of SEQ ID NO: 4. The sequence comparison between the

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amino acid sequence of HES1 from yeast and SEQ ID NO: 33 shows significant gaps and that the two proteins are of a different size, clearly indicating that Applicant has not provided any relevant identifying features linking the amino acid sequence of SEQ ID NO: 33 and the HES1 protein from yeast or their respective nucleic acid sequences.

Claims 16-21, 25-27 and 30-41 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/07/2004. Applicant's arguments filed 4/07/2005 have been considered but are not deemed persuasive.

Applicant asserts that the specification provides ample disclosure to enable a skilled artisan to make or use the claimed invention and that the invention need not be reduced to practice prior to filing given that the state of the art and the disclosure allow the practice of the invention to its full scope without undue burden (response page 12 to page 13 line 7).

The state of the art for computer analysis of nucleic acid sequences is unpredictable because there are a number of inaccuracies that arise when attempting to make function predictions for DNA sequences that have no known function other than that based on homology of which several that have been documented by researchers in the field. Further, Applicant's disclosure provides no working examples of a plant HES1 protein or what phenotype one of skill in the art could expect to produce when transforming a plant with any one of the claimed sequences.

Applicant contends that some experimentation would be required but that it would not be undue and only routine (response page 13). The lack of guidance and working examples in the specification combined with the state of the art would require that one of skill in the art perform undue trial and error experimentation, transforming a multitude of plants with a multitude of non-exemplified nucleic acid sequence to retrieve a non-specified phenotype.

Applicant contends that the references presented in the enablement rejection only reflect a general controversy in the art of homology based prediction and does not provide any support for the proposition that the claimed nucleic acids do not encode HES1 proteins (response page 14), and further asserts that the Fang reference does not suggest that the HES1 protein encoded by the nucleic acid sequences of the present invention could not be used to modulate phytosterol biosynthesis in a plant cell.

Applicant's attention is directed to lines 12-14 of the abstract of Fang where the authors clearly point out that the determination of the function of KES1p is the first direct insight into the biological role of any member of the oxysterol binding protein (OSBP) family, which includes HES1. Furthermore, the general problem of assigning function from structure is further exacerbated by the fact that the prior art does not support a clear function for the structure of the nucleic acids of the claims, because there is a lack of functional relatedness among yeast OSBP homologs that includes HES1, and that HES1 mutants in yeast alone or in combination with other OSBP mutations did not restore growth as did the KES1 homolog, further suggesting that HES1 alone would not produce a detectable phenotype in a transformed plant. In addition, a sequence comparison between the amino acid sequence of HES1 from yeast and SEQ ID NO: 33 shows significant gaps and that the two proteins are of a different size suggesting that isolated

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nucleic acid sequence SEQ ID NO: 4 encoding SEQ ID NO: 33 would require further undue trial and error experimentation to determine its' activity either *in vivo* or *in planta*.

In response to Applicant's assertion that Applicant need not teach conventional and well-known genetic engineering techniques in response to the Examiners point that Applicant has not performed the most routine of scientific procedures known in the art with respect to determining the biological function of HES1 (response page 15), see *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through a multitude of homologous nucleic acids and fragments thereof and test for some non-exemplified HES1 activity *in vivo* or some non-exemplified phenotype *in planta*.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 16, 17 and 25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 28-29 and 39 respectively of copending Application No.

10/793,639. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Please see attached sequence search showing instant SEQ ID NO: 33= copending SEQ ID NO: 625.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-21, 25-26 and 28-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-41 of copending Application No. 10/793,639. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the range of nucleic acid sequences encoding a plant HES1 protein or of a sequence that hybridizes to SEQ ID NO: 4, and of transformed plant species to

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obtain the instantly claimed range of nucleic acid sequences and transformed plants comprising sense or antisense constructs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
July 8, 2005

RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER

Russell Kallis

QY 361 NEKDEFTFRLAAMDLTGIGISDRGTGWRPDPSPAVDANPPYKVGEGJGL 414
 DB 361 NEKDEFTFRLAAMDLTGIGISDRGTGWRPDPSPAVDANPPYKVGEGJGL 414

RESULT 2
 US-09-248-796A-17983
 Sequence 17983, Application US/09248796A
 Patent No. 6747137

GENERAL INFORMATION:

APPLICANT: Kelch Weinrock et al

TITLE OF INVENTION: NUCLEIC ACID AND AMINO ACID SEQUENCES RELATING TO CANDIDA ALBICAN

FILE REFERENCE: 107196.132

CURRENT FILING DATE: 1999-02-12

PRIOR APPLICATION NUMBER: US 60/074,725

PRIOR FILING DATE: 1998-02-13

PRIOR APPLICATION NUMBER: US 60/096,409

PRIOR FILING DATE: 1998-08-13

NUMBER OF SEQ ID NOS: 28208

SEQ ID NO 17983

LENGTH: 444

TYPE: PRT

ORGANISM: Candida albicans

US-09-248-796A-17983

Query Match 42.3%; Score 916.5; DB 4; Length 444;

Best Local Similarity 50.6%; Pred. No. 5.6e-88;

Matches 195; Conservative 57; Mismatches 98; Indels 35; Gaps 10;

QY 6 EASAVPAASAKTSWSPFLKSIASFNGDLSLTAPPFLSTSTLTERSAVYCEHPALFVAPA 65
 DB 19 KSSSEETAKSSWTSFLKSIASFNGDLSLTAPPFLSTSTLTERSAVYCEHPALFVAPA 78

QY 66 ---REDDPAK-----RALIYLVKMFSLTHQOYCSRSSEKLGSEKPLNPLFGEVFG 113
 DB 79 LKTTENPTKEIEEALNLOQMIVTWMFISTLKSQYCSRSSEKLGSEKPLNPLFGEVFG 138

QY 114 KMEDEDEVRILISHOVSHHPATAYSIYNEKGVLOQYNAOKASFSST--IQVQOLGH 172
 DB 139 KM-QDKTGSTDLVSSQVSHHPATAYSIYNEKGVLOQYNAOKASFSST--IQVQOLGH 197

QY 173 AYLSLTPPGKANNEDREHYLITLPHNLSLYGTPEVELEKSCIKASSTGYISKIDF 232
 DB 198 ALIKY--PRID-----EFLITLPPHIEGLITAPFELEGISYIQASSGHIAVIEY 248

QY 233 SGKWLSGKKNTPSAVLKYE--SDGEKNPLYTADQWSSSFTI---RDARAKDIEFT 285
 DB 249 SGRGWISGKKNTPSAVLKYE--SDGEKNPLYTADQWSSSFTI---RDARAKDIEFT 307

QY 286 TISNKTTPPLVAPLDEODEWETRRARVDVAALIERGDMETSNATKIEVAQRELRKKE 345
 DB 308 DASKTPTPHLQVPRIEQHLESRKAMPKVAEALIKSDYNLATEKTLLENQKRLKKE 367

QY 346 KEQGEWERRPFRKRVN---EKDEP 366
 DB 368 KDAGITWETWTFKIDYINDADAP 392

RESULT 3
 US-09-614-221A-626
 Sequence 626, Application US/09614221A
 Patent No. 6723837

GENERAL INFORMATION:

APPLICANT: Karunanandaa, Balasubramanian

APPLICANT: Yu, Jaehyuk

APPLICANT: Kishore, Ganesh M.

TITLE OF INVENTION: NUCLEIC ACID MOLECULES AND OTHER MOLECULES ASSOCIATED

FILE REFERENCE: 16516.075

CURRENT APPLICATION NUMBER: US/09/614,221A

CURRENT FILING DATE: 2000-07-12

PRIOR APPLICATION NUMBER: US 60/142,981
 PRIOR FILING DATE: 1999-07-12
 NUMBER OF SEQ ID NOS: 626
 SEQ ID NO 626
 LENGTH: 434
 TYPE: PRT
 ORGANISM: Saccharomyces cerevisiae

US-09-614-221A-626

Query Match

Best Local Similarity 46.4%; Pred. No. 1.1e-87;

Matches 201; Conservative 60; Mismatches 105; Indels 67; Gaps 11;

QY 13 ASKTSWSPFLKSIASFNGDLSLTAPPFLSTSTLTERSAVYCEHPALFVAPA----- 66
 DB 5 ASSSMTWSPFLKSIASFNGDLSLTAPPFLSTSTLTERSAVYCEHPALFVAPA----- 64

QY 67 -----REDDPAKALVLMKPLSTLHQQOYCSRSSEKLGSEKPLNPLFGEVFGKVI 116
 DB 65 KDHCFFDENWSEKVAQMLAVRWFISTLRQYCSRSSEKLGSEKPLNPLFGEVFGKVI 124

QY 117 BDE--DVGERTLISHOVSHHPATAYSIYNEKGVLOQYNAOKASFSST--TIQVQOLGH 172
 DB 125 NDEHEPEFETVLSQVSHHPATAYSIYNEKGVLOQYNAOKASFSST--TIQVQOLGH 184

QY 173 AYLSLTPPGKANNEDREHYLITLPHNLSLYGTPEVELEKSCIKASSTGYISKIDF 232
 DB 185 VLKTI---KD-----EYLLITPPHIEGLITAPFELEGISYIQASSGHIAVIEY 233

QY 233 SGKWLSGKKNTPSAVLKYE--SDGEKNPLYTADQWSSSFTI---RDARAKDIEFT 285
 DB 234 SGRGWISGKKNTPSAVLKYE--SDGEKNPLYTADQWSSSFTI---RDARAKDIEFT 289

QY 286 TISNKTTPPLVAPLDEODEWETRRARVDVAALIERGDMETSNATKIEVAQRELRKKE 345
 DB 290 DSKTPTPHLQVPRIEQHLESRKAMPKVAEALIKSDYNLATEKTLLENQKRLKKE 349

QY 346 KEQGEWERRPFRKRVN---EKDEP 366
 DB 350 RYKGVQWRPFRKRVN---EKDEP 366

QY 365 R---TGWVRPD 393
 DB 410 KDAGITWETWTFKIDYINDADAP 392

RESULT 4
 US-09-248-796A-17971
 Sequence 17971, Application US/09248796A
 Patent No. 6747137

GENERAL INFORMATION:

APPLICANT: Kelch Weinrock et al

TITLE OF INVENTION: NUCLEIC ACID AND AMINO ACID SEQUENCES RELATING TO CANDIDA ALBICAN

FILE REFERENCE: 107196.132

CURRENT APPLICATION NUMBER: US/09/248,796A

CURRENT FILING DATE: 1999-02-12

PRIOR APPLICATION NUMBER: US 60/074,725

PRIOR FILING DATE: 1998-02-13

PRIOR APPLICATION NUMBER: US 60/096,409

PRIOR FILING DATE: 1998-08-13

NUMBER OF SEQ ID NOS: 28208

SEQ ID NO 17971

LENGTH: 360

TYPE: PRT

ORGANISM: Candida albicans

US-09-248-796A-17971

Query Match 15.2%; Score 329.5; DB 4; Length 360;

Best Local Similarity 28.6%; Pred. No. 5.8e-26;

Matches 88; Conservative 65; Mismatches 126; Indels 29; Gaps 10;

QY 31 DISSITAPPFLSTSTLTERSAVYCEHPALFVAPARBDPAKALVLMKPLSTHQQYC 90